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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,162	02/23/2004	Assaf Govari	BIO-5042	8493

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EXAMINER

CWERN, JONATHAN

ART UNIT	PAPER NUMBER
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3737

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/785,162	Applicant(s) GOVARI ET AL.	
	Examiner JONATHAN G. CWERN	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-21, 23, 24, 35-37, 39-42, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-21, 23, 24, 35-37, 39-42, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 12 is objected to because of the following informalities:

In claim 12, lines 5-6, the word and is repeated twice, one of the words "and" should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16, 18-21, 23-24, 35-37, 39-42, and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim (US 6083170).

Ben-Haim discloses a self-aligning catheter. Ben-Haim shows a catheter with a position sensor near the distal tip, and a deflection device to deflect the distal tip of the catheter. Signal processing circuitry drives alignment circuitry to transmit steering signals to the deflection device, causing it to deflect the distal tip of the catheter. The position sensor can comprise coils which generate signals in response to a magnetic field as described in US 5391199 (column 8, line 60-column 9, line 60). It should be noted that this same reference is referred to in applicant's specification as a suitable position sensor for applicant's invention, and thus this position sensor will generate a signal indicative of six dimensions of location and orientation information. The deflection device can include mechanical components. The system automatically controls these mechanical elements which deflect the distal tip of the catheter, and as the system functions automatically it can be considered a robot. As the catheter tip can be deflected up and down by the tip deflection mechanism, an additional alignment mechanism is included which can rotate the catheter, and thus the distal tip. Thus the distal tip can be controllably deflectable in no more than two directions for any given rotation of the distal tip (Figure 8, and column 12, lines 40-65). A catheter advance mechanism is also employed to automatically control movement of the catheter in a direction into or out of the body, advancing or withdrawing the catheter (column 13, lines 39-50). This combination of different movement directions allows for movement with six degrees of freedom. The system further allows for operator interaction, with various user inputs for controlling different functions of the system or for manual control over the steering of the catheter (column 13, lines 50-67).

Ben-Haim (column 1, lines 50-55) also incorporates by reference Galel (US 5492131). Galel discloses a servo-catheter, and shows steering the catheter based on feedback from the position sensor. The catheter is steered by operating two servo motors located at the proximal end of the catheter which actuate a steering mechanism at the distal end (column 4, line 60-column 5, line 8).

While Ben-Haim does not explicitly refer to the use of robots, end-effectors, and thumb controls, Ben-Haim does refer to automatic control, and mechanical components which attach to the catheter and cause the distal tip of the catheter to deflect. That is, while Ben-Haim shows other embodiments where the catheter distal tip is deflected by direct electronic automatic control (column 9, lines 55-60), Ben-Haim also shows embodiments such as described above in which intermediate mechanical components are automatically controlled and used to deflect the distal tip of the catheter. Thus, one of ordinary skill in the art, at the time the invention was made would recognize that the distal tip of the catheter could be deflected in a number of different ways. Thus, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the system to use mechanical parts which operate with controls on the catheter (such as a thumb control) and driven automatically (by a robot/controller), as an obvious design choice. Furthermore, steerable catheters with thumb controls are well known in the prior art, as indicated in applicant's published specification ([0128]), and thus it would be obvious to use such a steerable catheter in the system of Ben-Haim. That is, one of ordinary skill in the art, could have modified the intermediate mechanical components for deflecting the distal tip of the catheter in Ben-Haim to

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operate with the well-known steerable catheters with thumb controls, by modifying the mechanical components to operate on those thumb controls to deflect the distal tip.

Furthermore, the use of the different mechanical mechanisms for deflecting the distal tip allow for a wide range of motion of the distal tip, so that it can be navigated within the patient's body or within a narrow channel such as a blood vessel. A variety of techniques are known in the art for controlling this motion, several of which are disclosed by Ben-Haim, and it would be obvious to move the distal tip in the catheter in any manner which would allow for safe navigation to the target through the desired path in the body.

Response to Arguments

Applicant's arguments filed 12/15/10 have been fully considered but they are not persuasive.

In regards to applicant's arguments that Ben-Haim et al. do not teach a thumb control, this is recognized by the examiner and thus the examiner provided the above 103 rejection. The examiner stands by the above points, and that one of ordinary skill in the art, could have modified the intermediate mechanical components for deflecting the distal tip of the catheter in Ben-Haim to operate with the well-known steerable catheters with thumb controls, by modifying the mechanical components to operate on those thumb controls to deflect the distal tip.

In regards to applicant's arguments that Ben-Haim et al. do not teach a catheter with a position sensor configured to generate a position signal indicative of six dimensions of location and orientation information, examiner respectfully disagrees.

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Applicant states that the position sensor of Ben-Haim et al. utilize an ultrasound transducer, however in column 9, lines 4-30, Ben-Haim et al. show that the position sensor comprises coils which generate signals in response to an externally-applied magnetic field. In this section Ben-Haim et al. also incorporate by reference US 5391199 which further shows obtaining six dimensions of location and orientation information (column 10, lines 45-50). It should be noted that this is the same reference which applicant refers to in applicant's own specification in regards to using a suitable position sensor for applicant's invention ([0123]). That is, Ben-Haim et al. use the same position sensor as applicant's invention, and thus the sensor of Ben-Haim et al. also obtains six dimensions of location and orientation information. Ben-Haim et al. also recognize in this section that other types of position sensors known in the art may be used. Furthermore, Ben-Haim et al. incorporate by reference Galel (US 5492131). Galel discloses a servo-catheter, and shows steering the catheter based on feedback from the position sensor, the position sensor obtaining both the position and orientation of the tip (six degrees). The catheter is steered by operating two servo motors located at the proximal end of the catheter which actuate a steering mechanism at the distal end (column 4, line 60-column 5, line 8).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN G. CWERN whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737